IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/559,503
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Filed:	December 5, 2005
Title:	INTELLIGENT LAMINATED PRESSURE SURFACE
Confirmation No.:	8720
Docket No.:	TJA-129US

VERIFICATION OF A TRANSLATION

Commissioner for Patents
P.O. Box 1450
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S I R :

I, he undersigned, Xavier Metzger Torelló, in the name of the *Metzger Technical Translations Bureau,* located in Barcelona (Spain), do solemnly and sincerely declare that:

1. My name and post office address are as stated below.

2. That a well-acquainted native English translator from our staff has carried out to the best of his knowledge and belief, a true correct translation from Spanish into English of this document.

3. The document for which the attached English translation is being submitted is a patent application on an invention entitled INTELLIGENT LAMINATED PRESSURE SURFACE.

4. The attached foreign language document was filed in the U.S. Patent and Trademark Office on December 5, 2005.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: March 20th 2006

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INTELLIGENT LAMINATE PRESSURE SURFACE

AIM OF THE INVENTION

This invention as explained in the title of this specification, relates to an improvement in the design and consequent use mainly for medical purposes of sheets with sensitive surfaces, which can receive information that can represent a risk for the wearer's skin.

BACKGROUND TO THE INVENTION

The detailed description herein is mainly intended for medical application.

Patients can suffer from ailments which prevent them from noticing superficial pain (on their skin). For example, a small stone in their shoe. If a healthy person detects it, they easily solve the situation by removing the stone, however, anyone suffering from some specific ailments may not detect this foreign body and this can cause a wound that can worsen. This is typical and occurs frequently among those suffering from diabetes mellitus (4% of the population) who may suffer so-called diabetic neuropathy, with a high level of insensitivity. The resulting wound is the so-called diabetic ulcer, which has serious effects requiring long and expensive care, including long rest periods. In the US, almost 60,000 diabetic feet are amputated each year.

There are other cases such as the so-called decubitus ulcers, caused by an infrequently varied position (dementia, unconscious or coma patients...) in bed or when seated. Different areas of the anatomy suffer excess pressure, since the bones press on the skin and this in turn, is pressed by the piece of furniture on which the patient is resting: bed, stretcher, chair. These pressures can exceed a certain risk level and have a temporary frequency, which it is usually interesting to know. That is, it may be advantageous to know how long the patient remains in the same position; in the event of a long period of immobility, the medical team must know this, assess the risk level, and if necessary, change the patient's position.

To summarise, it is a question of obtaining superficial pressure data relative to the patient, data that the patient does not provide by being the actual patient. Surfaces with sensors are known which operate on the basis of distributing resistances, mainly piezoresistors and piezoelectric elements. In order to adequately distinguish the pressure applied in each point, they produce considerable output signals with their electronic components, conversors and other added elements. This therefore makes a foot insole uncomfortable. In order to solve this situation, the surface of this invention

can discriminate each point with a hole, but the signals determining the risk contact can be much fewer, which considerably simplifies the conductive system.

There are also models based on elastic sheets with conductive areas, such as patent DE 4418775 A1 which registers manually adjustable pressure levels and is used in traumatology, and includes rigid elements next to the skin and is limited in discriminating small objects. Patents EP0286054A1 and DE8910258.4 U1, the latter being an insulating elastic sheet with rounded or oval holes and conductive buttons on the upper conductive surface which, vis-à-vis certain pressure, comes into contact with the lower conductive part thus activating an alarm, acting by area and discriminating areas with various holes. It measures a pressure level in each hole, and determines the risk pressures in pre-established areas. In diabetic feet, it does not accurately detect particularly small foreign risk objects, and neither does it assess the pressure frequencies, or claim a smart system or optical or radical conduction. The pressure surface model of this invention can overcome these drawbacks.

The pressure surface of this invention, via small output signals, can assess any risk pressure, by measuring various levels such as for example, 0, 1, 2, 3 or more, which, for example, in a liquid crystal reader, would be equivalent to four colours in each discriminated area, one colour for each level measured and facilitated by using a smart system.

DESCRIPTION OF THE INVENTION

The device of this invention consists of a laminate pressure surface (fig. 1) comprising a non-conductive elastic sheet (e), with an abundance of holes (the shape and number of which is not claimed) which cross it from top to bottom; on both sides of said sheet there are two faces (c and c') or conductive sheets covering at least the holes thereof.

An external pressure (for example, produced by the object lodged between the shoe and the sole) that exceeds a certain measurement, brings into contact the conductive faces that face each other through the holes, whereby the user knows that there has been at least one point of contact somewhere in sheet (e).

The areas of the conductive faces facing the holes have a suitable relief r (figure 1) for facilitating said conductive contact (flat, pyramidal, conical, etc.); no particular shape is claimed; also optionally a mobile conductive object can be placed inside the holes (m.o. in Figure 1) to facilitate said contact.

The size and distribution of the holes makes it possible to detect any object whose pressure is sufficient to put the wearer's skin at risk.

The conductive faces can be insulated on the outside thereof (b and b') to stabilise the system, and the face (b) directly receiving the impact can be given a relief that facilitates small objects approaching the holes.

At least one of the conductive faces is distributed by areas (z, in Fig. 2), and the contacts with the holes reach these areas, and 1, 5, 10 or all the holes can reach them, according to the accuracy with which the user desires to know the location of the impacts (greater to less respectively). Each conductive area emits a signal (fig. 4).

DESCRIPTION OF THE DRAWINGS:

In order to improve the understanding of this specification description, several drawings are attached which represent, merely as an illustrative example, a practical embodiment of the smart laminate pressure surface (SPLI, in its abbreviated form in Spanish).

Figure 1. "P.L." section of smart laminate pressure surface, from the side, with insulating sheets (b) and (b'), conductive sheets (c) and (c'), elastic sheet (e), holes (o), relief (r) and an optional mobile object (e.g. a ball) which is also conductive (m.o).

Figure 2. Laminate pressure surface broken down into sheets: from top to bottom, in perspective (b), (c), (e) broken down towards the right, (c') and (b').

Figure 3. "P.L." section of smart laminate pressure surface, from the side, with insulating sheets (b), (f), (b'), conductive sheets (c), (Fs), (Fi), (c'), elastic sheets (e) and holes (o).

Figure 4. Basic circuit. "C.B." conductor, in this case, electrical: with generator, wiring, conducting areas (z) from which a signal is emitted, alarm devices (AL), reading device (l.c.), integrated circuit (c.i.), antenna (a) and as an example on the right of the drawing, holes (o) in an elastic sheet (e) that can receive a conductive area (z).

Figure 5. Smart laminate pressure surface, with its sheets broken down from top to bottom and in perspective: (b), (c), (e) broken down also towards the right, (Fs), (f), (Fi), (e) also broken down towards the right, (c') and (b'); (p) direct pressure receiver (objects, foot, etc.); (c') and (Fs) are distributed according to areas (z).

Figure 6. "C.T." section of smart laminate pressure surface, in the event of two possible foreign objects with different pressure: left, minimum pressure (m) and right, maximum pressure (M); top, pressure action "P", and bottom, pressure resistance "R", both with their indicator vectors, and the various sheets from top to bottom: (b), (c), (e), (Fs), (f), (Fi), (e), (c'), (b').

DESCRIPTION OF A PREFERRED EMBODIMENT:

The device of this invention is a smart laminate pressure surface (SPLI in its abbreviated form in Spanish) comprising a non-conductive elastic sheet (e), with an abundance of holes (the shape and number of which are not claimed) that cross it from top to bottom; on both sides of said sheet there are two sheets, (c and c') the inner faces of which are conductive, and which mainly cover said holes.

A certain pressure (for example, as mentioned above, a shoe insole; the pressure produced by the object that lodged between the shoe and the bottom of the foot), brings into contact the conductive faces facing each other through the holes, therefore forming a conductive circuit.

By means of these three sheets a pressure level can be measured, with each new level to be measured involving another laminate pressure group such as the one just described, backing onto it, (fig. 3) and with an adjustment of the corresponding physical-mechanical properties.

The areas of the conductive faces facing the holes have a suitable relief (r, fig. 1) for facilitating said conductive contact (flat, pyramidal, conical, etc.), which is not claimed; said contact is also facilitated by optionally installing a mobile object, for example, rounded: "m.o." in fig. 1, which goes inside the holes, and neither the shape or composition of said object is claimed.

The size and distribution of the holes makes it possible to notice any object whose pressure puts the wearer's skin at risk.

The face directly receiving the impacts (always "b", in the various drawings) has a relief that facilitates small objects approaching the holes.

The conductive faces are distributed in areas ("z" in figs. 2 and 4), and the contacts with the holes reach these areas, and 1, 5, 10 or all the holes can reach them, according to the accuracy with which the user desires to know the location of the impacts (respectively from greater to lesser pressure). Each conductive area emits a signal (fig. 4). The size and distribution of the areas on each conductive face are adjusted to the space to be measured. (Let's say the system is prepared to detect any small risk object, but it may be of interest that the location of the object is more or less accurate).

Fig. 6 shows on the left-hand side a "minimum contact" (m) with a foreign object, via the external pressure for example of a foot, which deforms the laminate pressure surface downwards, that allowing the inner face of sheet (c) to come into contact with the upper face (Fs) of f, both conductive faces, which the circuit detects. And the same figure 6 shows, on the right-hand side, an example of "maximum" contact which brings

the lower face (Fi) of f into contact with the upper face (c') of both conductive elements, and the circuit also detects this contact. The smart laminate pressure surface (SPLI, in its abbreviated form in Spanish) indicates to the wearer that there are risk objects in his/her shoe and that he/she can remove them. As for the shape of the laminate pressure surface, this can be standard or made to measure. For example, insoles for various shoe sizes; surfaces of the size of a hospital bed sheet, or smaller surfaces, to monitor particular areas of the patient's bed.

The circuit comprises an accurate generator, either electrical (fig. 4), or optical or both combined, since the signals conducted may be of the three types.

The smart laminate pressure surface (SPLI, in its abbreviated form in Spanish) can also assess pressure or impact frequencies, with its varied measurements, and the interruption frequencies.

All the information is gathered (fig. 4) via the wiring and taken to alarm devices (AL) (that can be optical, acoustic, or combined optical and acoustical devices) or to reading devices (l.c) also in a smart integrated circuit (c.i.) which interprets them according to the program, and notifies the wearer. The signals can be conducted or radiated (a).

Finally, if it is desirable to determine the location of the pressure contacts, the two conductive faces are distributed according to areas, of varying size, with a signal being emitted from each area, although there may be several simultaneous contacts, and each area can comprise one, several or all of the holes.

If it is desirable to measure more than one pressure level, two or more pressure surfaces can be stacked, sandwich style, joining the faces of the laminate pressure surfaces that come into contact, and just considering the modifications made.

Its application is mainly medical: such as in the prevention of diabetic foot and decubitus ulcers. It is also intended for non-medical applications: where it is desirable to detect one or several pressures. Acting as a mechanism or with a servomechanism, to prevent a risk (for example in safety and footwear), for keyboard operation, and for diagnosing pressure distributions over a surface.